13 July 2011
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Veterinary Medicines and Product Data Management

EMEA/V/A/060

Committee for medicinal products for veterinary use (CVMP)

Opinion following an Article 34 referral for Doxyfar 50% and associated names

International non-proprietary name (inn): doxycycline hyclate

Background information

Doxycycline is a semi-synthetic tetracycline antibiotic. Tetracyclines have broad spectrum activity inhibiting Gram-positive and Gram-negative bacteria, *mycoplasmas*, *chlamydiae*, *rickettsias* and some *protozoa*. Doxyfar 50 % and associated names is a powder for use in drinking water containing the active substance doxycycline hyclate 500 mg/g. The product is indicated for the treatment of certain infections of the respiratory tract in pigs and chickens.

Due to divergent national decisions taken by Member States regarding the target species, indications, amounts to be administered and withdrawal periods concerning the authorisation of Doxyfar 50% and associated names, on 18 June 2010 the United Kingdom referred the issue to the CVMP under Article 34(1) of Directive 2001/82/EC, in order to resolve divergences amongst the nationally authorised summary of product characteristics across the European Union.

The referral procedure started on 14 July 2010. The Committee appointed Mrs Ruth Kearsley as rapporteur and Dr Jiří Bureš as co-rapporteur. Further to the resignation of Mrs Ruth Kearsley as CVMP member, Ms Helen Jukes was appointed to replace her and took over the rapporteurship. Written explanations were provided by the applicant/marketing authorisation holder on 15 October 2010 and 8 March 2011.

Based on the rapporteurs' assessment of the currently available data, the CVMP considered that the benefit/risk profile for Doxyfar 50% and associated names remains positive subject to variation of the marketing authorisations in accordance with the summary of product characteristics, and therefore adopted a positive opinion on 4 May 2011.

The list of product names concerned is given in Annex I. The scientific conclusions are provided in Annex II, together with the amended summary of product characteristics in Annex III.

The final opinion was converted into a Decision by the European Commission on 13 July 2011.

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